

Simona Pelleriti

**REFERRAL FOR A PRELIMINARY
RULING OF THE EUROPEAN
COURT OF JUSTICE FROM AN
ARBITRAL TRIBUNAL: RECENT
DEVELOPMENTS IN LIGHT OF
CASE C-555/13 (*ORDER OF THE
COURT OF EUROPEAN UNION,
13 FEBRUARY 2014*)**

Estratto



Milano • Giuffrè Editore

COMMENTI E RASSEGNE

ORDER OF THE COURT OF JUSTICE OF EUROPEAN UNION (Eighth Chamber) of 13 February 2014 (request for a preliminary ruling from the Tribunal Arbitral - Portugal) — Case C-555/13 — Merck Canada Inc. v. Accord Healthcare Ltd, Alter SA, Labochem Ltd, Synthon BV, Ranbaxy Portugal (*) (**).

Request for a preliminary ruling - ‘Court or tribunal’ for the purposes of Article 267 TFEU - Tribunal Arbitral necessário - Admissibility - Regulation (EC) No 469/2009 - Article 13 - Supplementary protection certificate for medicinal products - Period of validity of a certificate - Maximum period of exclusivity.

Un tribunale arbitrale convenzionale non costituisce un organo giurisdizionale di uno Stato membro ai sensi dell’articolo 267 TFUE qualora non sia previsto un obbligo per le parti contraenti di affidare la soluzione delle proprie liti a un arbitrato. Tuttavia la Corte può dichiarare ricevibile il rinvio pregiudiziale proveniente da un tribunale arbitrale che sia istituito con legge, che abbia carattere permanente, che emetta decisioni vincolanti per le parti e la cui competenza non dipenda dall’accordo di queste ultime.

Le circostanze per cui le parti abbiano la possibilità di variare la forma, la composizione e le norme processuali riguardanti il tribunale arbitrale e quest’ultimo venga sciolto subito dopo aver emesso la propria decisione, non sono sufficienti ad escluderne il carattere permanente. Se, infatti, tale tribunale è istituito con legge e la normativa nazionale definisce e inquadra le norme processuali che esso applica, si deve considerare che esso disponga comunque di una competenza obbligatoria a titolo permanente.

THE COURT (Eighth Chamber),
composed of C.G. Fernlund, President of the Chamber, C. Toader (Rapporteur) and E. Jarašiūnas, Judges,
Advocate General: N. Jääskinen,
Registrar: A. Calot Escobar,
having decided, after hearing the Advocate General, to give a decision by reasoned order, pursuant to Article 99 of the Rules of Procedure of the Court of Justice,
makes the following

(*) Language of the case: Portuguese.

(**) Vedi la nota che segue di Simona Pelleriti.

Order

1. This reference for a preliminary ruling concerns the interpretation of Article 13 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1).

2. The request has been made in proceedings between Merck Canada Inc. ('Merck Canada') and Accord Healthcare Ltd, Alter SA, Labochem Ltd, Synthon BV and Ranbaxy Portugal - Comércio e Desenvolvimento de Produtos Farmacêuticos, Unipessoal Lda, concerning the maximum period of exclusivity granted by both the basic patent and the supplementary protection certificate ('the certificate') held by Merck Canada.

Legal context

3. Recital 9 to Regulation No 469/2009 is worded as follows:

'The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market ["MA"] in the [European Union].'

4. Article 2 of the regulation provides:

'Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [OJ 2001 L 311, p. 67] ... may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.'

5. Article 3 of the regulation states:

'A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

- (a) the product is protected by a basic patent in force;
- (b) a valid [MA] as a medicinal product has been granted in accordance with Directive 2001/83/EC ...;
- (c) the product has not already been the subject of a certificate;
- (d) the authorisation referred to in point (b) is the first [MA] as a medicinal product.'

6. With regard to the period of validity of the certificate, Article 13(1) to (3) of Regulation No 469/2009 provides:

'1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first [MA] in the [European Union], reduced by a period of five years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.'

The dispute in the main proceedings and the question referred for a preliminary ruling

7. According to the order for reference, on 11 October 1991, Merck Canada lodged an application in Portugal for a patent for the active ingredient montelukast sodium, present in particular in the medicinal products Singulair and Singulair junior. Following that application, Patent No 99 213 was granted to that company, on 2 October 1998, in Portugal.

8. Within the European Union, the first MA for a medicinal product containing that active ingredient was obtained in Finland on 25 August 1997.

9. On 3 February 1999, Merck Canada applied for a certificate with the Instituto Nacional da Propriedade Industrial (National Institute of Intellectual Property) for a medicinal product relating to Patent No 99 213. Following that application, Certificate No 35 was granted to that company on 10 January 2000 for the active ingredient montelukast sodium.

10. According to the documents before the Court, on 6 November 2012, Merck Canada brought an action before the Tribunal Arbitral necessário seeking to compel, *inter alia*, the defendants in the main proceedings to abstain from producing, importing and/or launching on the Portuguese market generic drugs containing the abovementioned active ingredient.

11. In support of its action, Merck Canada relies, pursuant to Article 13 of Regulation No 469/2009, on the full period of validity of Certificate No 35, which is to run until 17 August 2014. It bases its reasoning on the fact that, under Article 13, the certificate is to take effect at the end of the lawful term of the basic patent, which was to expire on 2 October 2013, being 15 years after the date on which that patent was granted in Portugal. According to Merck Canada, the certificate was to take effect on 3 October 2013, for a period of 10 months and 15 days, until 17 August 2014, even if, under such a period which falls to be added to that of the patent it holds, that company may enjoy a period of exclusivity over the abovementioned active ingredient for a period which is greater than 15 years. As a result, the generic drugs produced by the defendants in the main proceedings should not be placed on the Portuguese market before the expiry date of that certificate.

12. By contrast, the defendants in the main proceedings claim that the aim of Regulation No 469/2009 is to guarantee the holder of both a patent and a certificate a maximum period of 15 years of exclusivity from the first MA, in the European Union, for the medicinal product in question.

13. Considering that the nature of the case required that it be processed within the shortest period possible, the Tribunal Arbitral necessário requests the application of the provision of Article 105 of the Rules of Procedure of the Court on the expedited procedure.

14. In those circumstances, the Tribunal Arbitral necessário decided to stay the proceedings and to refer the following question to the Court:

‘Is Article 13 of Regulation No 469/2009 to be interpreted as permitting, by means of a [certificate] for medicinal products, the period for exclusive exploitation of the patented invention to be more than 15 years from the date of the first authorisation to place the medicinal product in question on the market within the Community (not including the extension provided for in Article 13(3) of that regulation)?’

The question referred for a preliminary ruling

Admissibility

15. First, it must be examined whether the Tribunal Arbitral necessário should be considered to be a court or tribunal for the purposes of Article 267 TFEU.

16. In that regard, it should be noted that, according to settled case-law of the Court, in order to determine whether a body making a reference is a ‘court or tribunal’ within the meaning of Article 267 TFEU, which is a question governed by EU law alone, the Court takes account of a number of factors, such as whether the body is established by law, whether it is permanent, whether its jurisdiction is compulsory, whether its procedure is *inter partes*, whether it applies rules of law and whether it is independent (see C-394/11 *Belov* [2013] ECR, paragraph 38 and the case-law cited).

17. It should also be stated that a conventional arbitration tribunal is not a ‘court or tribunal of a Member State’ within the meaning of Article 267 TFEU where the parties are under no obligation, in law or in fact, to refer their disputes to arbitration and the public authorities of the Member State concerned are not involved in the decision to opt for arbitration nor required to intervene of their own accord in the proceedings before the arbitrator (Case C-125/04 *Denuit and Cordenier* [2005] ECR I-923, paragraph 13 and the case-law cited).

18. However, the Court has held admissible preliminary questions referred to it by an arbitral tribunal, where that tribunal had been established by law, whose decisions were binding on the parties and whose jurisdiction did not depend on their agreement (see, to that effect, Case 109/88 *Danfoss* [1989] ECR 3199, paragraphs 7 to 9).

19. In the main proceedings, it is clear from the order for reference that the jurisdiction of the Tribunal Arbitral necessário does not stem from the will of the parties, but from Law No 62/2011 of 12 December 2011. That law confers upon that tribunal compulsory jurisdiction to determine, at first instance, disputes involving industrial property rights pertaining to reference medicinal products and generic drugs. In addition, if the arbitral decision handed down by such a body is not subject to an appeal before the competent appellate court, it becomes definitive and has the same effects as a judgment handed down by an ordinary court.

20. The Member State at issue has therefore chosen, in the context of its procedure autonomy and with a view to implementing Regulation No 469/2009, to confer the jurisdiction for this type of dispute upon another body rather than an ordinary court (see, to that effect, Case 246/80 *Broekmeulen v Huisarts Registratie Commissie* [1981] ECR 2311, paragraph 16).

21. It is, moreover, apparent from the order for reference that the conditions laid down in the case-law of the Court referred to in paragraph 16 of the present order, relating to whether the body is established by law, whether its procedure is *inter partes*, whether it applies rules of law and whether it is independent, are met.

22. It is clear from the order for reference that Article 209(2) of the Constitution of the Portuguese Republic lists the arbitral tribunals among those entities capable of exercising an adjudicative function and that the Tribunal Arbitral necessário was established by Law No 62/2011 of 12 December 2011.

23. Furthermore, according to the order for reference, the arbitrators are

subject to the same obligations of independence and impartiality as judges belonging to the ordinary courts and the Tribunal Arbitral necessário observes the principle of equal treatment and the adversarial principle in the treatment of parties and gives its rulings on the basis of the Portuguese law on industrial property.

24. The Tribunal Arbitral necessário may vary in form, composition and rules of procedure, according to the choice of the parties. Moreover, it is dissolved after making its decision. It is true that, those factors may raise certain doubts as to its permanence. However, given that that tribunal was established on a legislative basis, that it has permanent compulsory jurisdiction and, in addition, that national legislation defines and frames the applicable procedural rules, it should be found that, in the present case, the requirement of permanence is also met.

25. Taking all of those considerations into account, it must be held that, in circumstances such as those of the main proceedings, the Tribunal Arbitral necessário fulfils all of the conditions laid down by the case-law of the Court, as set out in paragraphs 16 to 19 of the present order, and must be considered to be a court or tribunal for the purposes of Article 267 TFEU.

Substance

26. Pursuant to Article 99 of its Rules of Procedure, where the reply to a question referred to the Court for a preliminary ruling may be clearly deduced from existing case-law or admits of no reasonable doubt, the Court may at any time, on a proposal from the Judge-Rapporteur and after hearing the Advocate General, decide to rule by reasoned order.

27. The Court considers that to be the case in the present proceedings and holds that, taking into account the making of the present order, it is not necessary to rule on the application for an expedited procedure made by the referring court (see, to that effect, order in C-503/07 P Saint-Gobain Glass Deutschland v Commission [2008] ECR I-2217, paragraph 45). The answer to the question referred by the Tribunal Arbitral necessário leaves no room for reasonable doubt and may, in addition, be clearly deduced from existing case-law, *inter alia* from the order in Case C-617/12 Astrazeneca [2013] ECR.

28. By its question, the Tribunal Arbitral necessário essentially asks whether Article 13 of Regulation No 469/2009, when read in conjunction with recital 9 thereto, must be interpreted as meaning that it precludes the holder of both a patent and a certificate from relying on the entire period of validity of the certificate, calculated in accordance with Article 13, in a situation where, pursuant to such a period, it would enjoy a period of exclusivity as regards an active ingredient, of more than 15 years from the first MA, in the European Union, of a medicinal product consisting of that active ingredient, or containing it.

29. An affirmative answer to that question follows from a literal interpretation of Article 13 of Regulation No 469/2009, read in conjunction with recital 9 thereto.

30. That interpretation was also confirmed most recently in the order in Astrazeneca, paragraph 42 of which provides that the holder of both a patent and a supplementary protection certificate should not be able to enjoy more than 15 years of exclusivity from the time the first MA, in the European Union, of the medicinal product concerned.

31. Furthermore, it should be recalled that the wording ‘first authorisation to

place the product on the market in the [European Union]’, for the purposes of Article 13(1) of Regulation No 469/2009, make reference to the first MA granted in any Member State and not to the first authorisation granted in the Member State of the application. Only that interpretation ensures that the extension of protection of the product covered by the certificate will expire at the same time in all of the Member States in which the certificate was granted (see, to that effect, Case C-127/00 Hässle [2003] ECR I-14781, paragraphs 74, 77 and 78).

32. In the main proceedings, it is not in dispute that the first MA, in the European Union, of medicinal products containing the active ingredient protected by the basic patent of which Merck Canada is the holder was granted on 25 August 1997 in Finland.

33. As a result, irrespective of the date on which the basic patent was granted in Portugal and the theoretical validity period of the certificate resulting from the application of Article 13 of Regulation No 469/2009, the maximum period of exclusivity conferred by both Patent No 99 213 and Certificate No 35 cannot exceed a total duration of 15 years, calculated from 25 August 1997.

34. In the light of the foregoing considerations, the answer to the question referred is that Article 13 of Regulation No 469/2009, when read in conjunction with recital 9 thereto, must be interpreted as meaning that it precludes the holder of both a patent and a certificate from relying on the entire period of validity of the certificate, calculated in accordance with Article 13, in a situation where, pursuant to such a period, it would enjoy a period of exclusivity as regards an active ingredient, of more than 15 years from the first MA, in the European Union, of a medicinal product consisting of that active ingredient, or containing it.

Costs

35. Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court.

On those grounds, the Court (Eighth Chamber) hereby rules:

Article 13 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, read in conjunction with recital 9 to the same regulation, must be interpreted as meaning that it precludes the holder of both a patent and a supplementary protection certificate from relying on the entire period of validity of such a certificate, calculated in accordance with Article 13, in a situation where, pursuant to such a period, it would enjoy a period of exclusivity as regards an active ingredient, of more than 15 years from the first authorisation to be placed on the market, in the European Union, of a medicinal product consisting of that active ingredient, or containing it.

Referral for a Preliminary Ruling of the European Court of Justice from an Arbitral Tribunal: recent developments in light of Case C-555/13.

SUMMARY: 1. Introduction: is Case C-555/13 an opening to the admissibility of a request for preliminary ruling from private arbitrators? — 2. The meaning of the expression “courts or tribunals” under Article 267 TFEU. — 3. The order of the European Court of Justice in Case C-555/13. — 4. The case law of the European Court of Justice about requests for preliminary ruling by Arbitral Tribunals. — 5. Arguments in support and against the traditional position of the European Court of Justice. — 6. Conclusion.

1. Introduction: is Case C-555/13 an opening to the admissibility of a request for preliminary ruling from private arbitrators?

This paper aims to analyse a recent order of the European Court of Justice (ECJ or Court) that declares the admissibility of a request for a preliminary ruling by an arbitral tribunal under article 267 TFEU ⁽¹⁾, as well as to understand if on this occasion the Court distanced itself from its traditional approach.

Although the ECJ already stated in more than one case that arbitrators are not entitled to resort to the Court for a preliminary ruling ⁽²⁾, this topic is still highly discussed among academics ⁽³⁾ especially by those who criticize the reasoning through which the Court denied the authorisation.

The consequences of the Court's traditional approach are significant if we consider how tight the link between arbitration and European Union law has become in the last decades due to i) the expansion of arbitration as the preferred

⁽¹⁾ Merck Canada Inc. v. Accord Healthcare Ltd and others, Case C-555/13 [2014] ECR I-0000.

⁽²⁾ Nordsee Deutsche Hochseefischerei GmbH v Reederei Mond Hochseefischerei Nordstern AG & Co. KG and Reederei Friedrich Busse Hochseefischerei Nordstern AG & Co. KG, Case 102/81 [1982] ECR 01095; Gemeente Almelo and Others v Energiebedrijf Ijsselmij, Case C-393/92 [1994] ECR I-1477; Guy Denuit and Betty Cordenier v Transorient - Mosaique Voyages et Culture SA, Case -125/04 [2005] ECR I-00923.

⁽³⁾ See among others: W. P. GORMLEY, *The Future Role of Arbitration within the EEC: The Right of an Arbitration to Request a Preliminary Ruling pursuant to Article 177*, *Saint Louis University Journal*, 1968, 4, p. 550; G. BEBR, *Arbitration Tribunals and Article 177 of the EEC Treaty*, *Common Market Law Review*, 1985, p. 489; X. DE MELLO, *Arbitrage et droit communautaire*, *Revue de l'arbitrage*, 1982, p. 390; M. FRIEND, *EEC Law, Preliminary Rulings and Arbitrators*, *The Law Quarterly Review*, 1983, p. 356; L. IDOT, *Arbitration and EC law*, *International Business Law Journal*, 1996, p. 561; C. BAUDENBACHER, *Enforcement of EC Competition Rules by Arbitration Tribunals Outside the EU*, *European Competition Law Annual 2001*, Oxford, p. 341; L. IDOT, *Arbitration courts*, *European Competition Annual 2001*, Oxford, p. 285; G. CHABOT, *Un tribunal arbitral conventionnel ne constitue pas une juridiction au sens de l'article 234 CE*, *La Semaine juridique - édition générale*, 2005, II, p. 10079H. VAN HOUTTE, *Arbitration and Arts. 81 and 82 EC Treaty? A State of Affairs*, *Asa Bulletin*, 2005, p. 431; C. RASIA, *Pregiudiziale comunitaria e giudizio arbitrale: nuovo confronto tra gabbie ideologiche, funzionalità degli scambi, esigenze di tutela effettiva*, *Il Corriere giuridico*, 2006, p. 21; E. F. RICCI, *Arbitrato volontario e pregiudiziale comunitaria*, *Rivista di diritto processuale*, 2006, p. 710; M. OLİK - D. FYBACH, *The Competence of Investment Arbitration Tribunal to seek Preliminary Ruling from the European Courts*, *Czech Yearbook of International Law*, 2011; S. H. ELSING, *References by Arbitral Tribunals to the European Court of Justice for Preliminary Rulings*, *Austrian Yearbook on International Arbitration*, 2013, p. 45.

method of dispute settlement in the law of business transactions and ii) the increasing effect of EU law on commercial relationships ⁽⁴⁾.

Thus, the refusal to admit requests for a preliminary ruling by arbitral tribunals may undermine the uniform application of EU law within the single market: in other words, denying the possibility for arbitrators to go before the Court for a preliminary ruling means running the risk that EU law is not applied correctly to awards which are binding for the parties.

After analyzing the order of the ECJ in Case C-555/13, the paper will deal with the main case law on this theme and with the principal argumentations in favour and against the Court's interpretation among academics. As it will be better explained in the next paragraphs, a crucial point of the ongoing debate is to understand whether the absence of an independent right of reference for arbitrators is an obstacle to the uniform application of EU law and whether such a right should be explicitly recognised.

2. *The meaning of the expression "courts or tribunals" under Articles 267 TFEU.*

Before proceeding with the analysis of the order subject to this commentary, it is opportune to describe, first of all, the content and purpose of article 267 TFEU, which regulates the handling of a request for preliminary ruling before the ECJ ⁽⁵⁾.

In order to guarantee the uniform interpretation and application of EU law, article 267 TFEU confers on any court or tribunal of a Member State the right to resort to the ECJ for a preliminary ruling concerning i) the interpretation of the Treaties or ii) the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union ⁽⁶⁾.

The main issue related to the application of this article concerns the vagueness of the term "*court or tribunal of a Member State*".

In the *Vaasseen*, decision ⁽⁷⁾ for the first time the Court offered an explanation about the interpretation of this expression, indicating the characteristics a body seeking reference to the ECJ should have in order to comply with the requirements

⁽⁴⁾ C. BAUDENBACHER - I. HIGGINS, *Decentralization of EC Competition Law Enforcement and Arbitration*, 8 *Colum. J. Eur. L.* 1, 2002, p. 16.

⁽⁵⁾ For a deepen study of the procedure of preliminary ruling see: R. BARENTS, *Directory of EU Case-law on the Preliminary Ruling Procedure*, *Kluwer Law International*, 2009; B. MORTEN - F. NIELS, *Preliminary References to the European Court of Justice*, Oxford, 2014.

⁽⁶⁾ Art. 267 TFEU: "*The Court of Justice of the European Union shall have jurisdiction to give preliminary rulings concerning:*

(a) the interpretation of the Treaties;

(b) the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union;

Where such a question is raised before any court or tribunal of a Member State, that court or tribunal may, if it considers that a decision on the question is necessary to enable it to give judgment, request the Court to give a ruling thereon.

Where any such question is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal shall bring the matter before the Court.

If such a question is raised in a case pending before a court or tribunal of a Member State with regard to a person in custody, the Court of Justice of the European Union shall act with the minimum of delay."

⁽⁷⁾ G. Vaassen-Göbbels (a widow) v Management of the Beambtenfonds voor het Mijnbedrijf, Case 61/65 [1966] ECR 262.

of article 267 TFEU. On that occasion the Court ruled about the admissibility of the reference for a preliminary ruling from the arbitration court of the pension fund for non-manual workers of The Netherlands (*Scheidsgerecht van het Beambtenfonds voor her Mijnbedrijf*).

The Court stated that, in some circumstances, the expression “court or tribunal of a Member State” can include bodies other than ordinary courts of law, in particular when such bodies: i) are established by law, ii) are permanent, iii) their jurisdiction is compulsory, iv) their procedure is *inter partes*, v) apply rules of law and vi) are independent ⁽⁸⁾.

According to these criteria, the Court ruled in favour of the admissibility of the reference by the *Scheidsgerecht* due to the mandatory obligation of the parties to resort to the arbitration court of the pension in settlement of disputes related to health insurance issues. Moreover, that tribunal was established under Dutch law, it was permanent, it was bound to adhere to rules of adversarial procedure similar to those used by ordinary courts, and its procedure contemplated the involvement of public authorities.

On further occasions, the Court declared admissible the request for a preliminary ruling from bodies other than an ordinary court of law. In *Broekmeulen* ⁽⁹⁾, the ECJ accepted a reference from the Dutch Appeals Committee for General Medicine, since it had in its view all the requirements set out in the *Vaasee* decision. Indeed, the Committee was established by the Royal Netherlands Society for the Promotion of Medicine, operated with the consent and cooperation of public authorities, and it delivered on the basis of an adversarial procedure decisions that were final.

The ECJ accepted also the reference coming from an industrial arbitration board that had jurisdiction in disputes between parties to collective agreements entered into between employees’ and employers’ organisations ⁽¹⁰⁾. The Court emphasized that the referring body was established by law, that disputes were subject to standard rules, that its decisions were final, and that the parties did not have discretion as to the composition of the board.

On the basis of the same criteria defined in *Vaasee*, the Court ruled in favour of the admissibility of the requests coming from an independent acting immigration officer ⁽¹¹⁾.

⁽⁸⁾ These criteria have been recently recalled in several orders where the ECJ restated that: “According to settled case-law, in order to determine whether a body making a reference is a ‘court or tribunal’ for the purposes of Article 267 TFEU, which is a question governed by Union law alone, the Court takes account of a number of factors, such as whether the body is established by law, whether it is permanent, whether its jurisdiction is compulsory, whether its procedure is *inter partes*, whether it applies rules of law and whether it is independent (see, *inter alia*, Case C-54/96 *Dorsch Consult* [1997] ECR I-4961, paragraph 23; Case C-53/05 *Syfait and Others* [2005] ECR I-4609, paragraph 29; Case C-246/05 *Häupl* [2007] ECR I-4673, paragraph 16; and Case C-394/11 *Belov* [2013] ECR I-0000, paragraph 38)” (MF 7 a.s. v. MAFRA a.s., Case C-49/13 [2013] ECR I-0000. See also cases *Dorsch Consult*, C-54/96 [1997] ECR I-4961 and *Schmid*, Case C-516/99 [2002] ECR I-4573).

⁽⁹⁾ *C. Broekmeulen v. Huisarts Registratie Commissie*, Case 246/80 [1981] ECR 2311.

⁽¹⁰⁾ *Handels- og Kontorfunktionærernes Forbund I Danmark v. Dansk Arbejdsgiverforening*, Case 109/88, [1989] ECR 3199.

⁽¹¹⁾ *Nour Eddline El-Yassini v. Secretary of State for Home Department*, Case C-416/96 [1999] ECR I-1209.

On the contrary, it denied the right of reference by some administrative authorities: it is the case for Amtsgericht Heidelberg, a local court in charge of keeping the commercial register ⁽¹²⁾. The Court found that when the Amtsgericht made the reference there was no indication of an ongoing dispute pending before it between the parties. Having said that, the ECJ concluded that in that situation the Amtsgericht was performing a non-judicial function, but simply an administrative one.

The Court reached the same conclusion in regard to the Bezirksgericht Bregenz, an Austrian land registry body, which was required to make administrative decisions but not to settle a legal dispute ⁽¹³⁾. Indeed the registration of a contract of sale of land merely implied that the Bezirksgericht Bregenz determined whether the application complies with the conditions laid down by the local law for the registration of property rights in the land register, which cannot be considered as the exercise of a judicial function.

This approach has been reaffirmed in a case regarding the admissibility of the request for preliminary ruling from the Skatterättsnämnden, a Swedish revenue board for the application of taxes ⁽¹⁴⁾. The Court affirmed that: *“it has been consistently held that a national court may refer a question to the Court only if there is a case pending before it and if it is called upon to give judgment in proceedings intended to lead to a decision of a judicial nature (see Case 318/85 Greis Unterweger (1986) ECR 955, paragraph 4, and Case C-111/94 Job Centre (1995) ECR I-3361, paragraph 9). (...) It should be borne in mind, in particular, that at the time when an application for a preliminary decision is lodged with Skatterättsnämnden the taxpayer’s situation has not been the subject of any decision by the tax authorities. Skatterättsnämnden does not therefore have as its task to review the legality of the decisions of the tax authorities but rather to adopt a view, for the first time, on how a specific transaction is to be assessed to tax”*. Those factors lead to the conclusion that the Skatterättsnämnden performed an essentially administrative function.

3. The order of the European Court of Justice in Case C-555/13.

The question addressed to the Court for a preliminary ruling in Case C-555/13 regards the interpretation of Article 13 of Regulation No 469/2009 on the period of validity of the supplementary protection certificate for medicinal products.

The request has been made by the Tribunal Arbitral necessário (also the Tribunal) in the proceedings between Merck Canada Inc., a pharmaceutical company, which lodged an application in Portugal for a patent for the active ingredient montelukast sodium, and other pharmaceutical firms. The debate concerned whether Article 13 of Regulation No 469/2009 permits, by means of a certificate for medicinal products, the period for exclusive exploitation of the patented invention to be more than 15 years from the date of the first authorization to place a medicinal product on the European market.

⁽¹²⁾ HSB-Wohnbau, Case C-86/00 [2001] ECR I-5355.

⁽¹³⁾ Doris Salzmann, Case C-178/99 [2001] ECR I-4421.

⁽¹⁴⁾ Victoria Film A/S, Case C-134/97 [1998] ECR I-7023; Pierre Corbiau v Administration des Contributions, Case C-24/92 [1993] ECR I-1277.

Before entering into the merit of the question, the Court had obviously had to deal with the admissibility of such a request from the Tribunal Arbitral necessário under Article 267 TFEU. First of all the ECJ recalled the case-law which states that *“a conventional arbitration tribunal is not a ‘court or tribunal of a Member State’ within the meaning of Article 267 TFEU where the parties are under no obligation, in law or in fact, to refer their disputes to arbitration and the public authorities of the Member State concerned are not involved in the decision to opt for arbitration nor required to intervene of their own accord in the proceedings before the arbitrator (Case C-125/04 Denuit and Cordenier (2005) ECR I-923, paragraph 13 and the case-law cited)”*.

However, the characteristics of the Tribunal Arbitral necessário seem to fulfill the requirements of Article 267 TFEU. Indeed, the parties were obliged to go before that Tribunal according to the Portuguese law No 62/2011 of 12 December 2011, which confers upon the Tribunal Arbitral necessário the compulsory jurisdiction to determine, at first instance, disputes involving industrial property rights pertaining to reference medicinal products and generic drugs.

Furthermore, arbitrators must be independent and impartial in the same manner as judges belonging to the ordinary courts and the Tribunal Arbitral necessário observes the principle of equal treatment and the adversarial principle in the treatment of parties and gives its rulings on the basis of the Portuguese law on industrial property.

Hence, the Court concluded that *“from the order for reference that the conditions laid down in the case-law of the Court referred to in paragraph 16 of the present order, relating to whether the body is established by law, whether its procedure is inter partes, whether it applies rules of law and whether it is independent, are met”*, in consequence *“it must be held that, in circumstances such as those of the main proceedings, the Tribunal Arbitral necessário fulfils all of the conditions laid down by the case-law of the Court, as set out in paragraphs 16 to 19 of the present order, and must be considered to be a court or tribunal for the purposes of Article 267 TFEU”*.

The Court reached this conclusion even if it observed that other characteristics of the Tribunal Arbitral necessário existed that may raise certain doubts about its qualification as *“courts or tribunals”* under Articles 267 TFEU. In particular the ECJ observed that the parties had the freedom of varying the composition and rules of procedure of the Tribunal and that it would be dissolved after making its decision. However, the Court evaluated that despite all those factors, these did not provide enough weight for it to deny the request of referral for preliminary ruling.

4. The main case law of the European Court of Justice about requests for preliminary ruling by Arbitral Tribunals.

The order just mentioned reveals how important the distinction between compulsory and consensual jurisdiction is for the Court in order to decide which bodies can be considered courts or tribunals under article 267 TFEU.

This criterion has been used in many occasions by the ECJ in order to determine whether a request of referral for preliminary ruling from an arbitral tribunal was admissible. Without pretending to be exhaustive, only the most significant decisions on this topic will be mentioned hereafter.

In the leading case *Nordsee* ⁽¹⁵⁾, the Court underpinned the difference between a “state-organized” and a “non-statutory” arbitral tribunal. In the first case, in fact, arbitration tribunals effectively fulfil a role similar to that of courts in the national legal system and, like in *Vaasseen*, they can constitute a tribunal for the purpose of sending a preliminary reference to the ECJ ⁽¹⁶⁾.

If there is, instead, no obligation on the parties, in law or in fact, to refer their dispute to arbitral tribunal and that choice derives from a private agreement between them, without the involvement of the State, the Court excludes the possibility to ask for a preliminary ruling.

The Court pointed out that “*when the contract was entered into in 1973 the parties were free to leave their disputes to be resolved by the ordinary courts or to opt for arbitration by inserting a clause to that effect in the contract. From the facts of the case it appears that the parties were under no obligation, whether in law or in fact, to refer their disputes to arbitration.*”. Although the ECJ denied the right to request a preliminary ruling given the conventional nature of the arbitral tribunal, it recognised an indirect possibility to refer to the Court through the so call “golden bridge” alternative ⁽¹⁷⁾, which consists of the examination by national courts of the questions about the application of EU law raised during the arbitral proceedings “*either in the context of their collaboration with the arbitration tribunals, in particular in order to assist them, or in the course of a review of an arbitration award.*”.

This judgement was later confirmed in *Eco Swiss* ⁽¹⁸⁾, where the Court reaffirmed that “*arbitrators, unlike national courts and tribunals, are not in a position to request this Court to give a preliminary ruling on questions of interpretation of Community law*” and in the *Denuit* decision ⁽¹⁹⁾, where it ruled against the recognition of the “*Collège d’arbitrage de la Commission de Litiges Voyages*” as court or tribunal under art. 267 TFEU since “*in the main proceedings the parties are under no obligation, in law or in fact, to refer their disputes to arbitration and*

⁽¹⁵⁾ *Nordsee Deutsche Hochseefischerei GmbH v Reederei Mond Hochseefischerei Nordstern AG & Co. KG and Reederei Friedrich Busse Hochseefischerei Nordstern AG & Co. KG*, Case 102/81, *cit.*

⁽¹⁶⁾ C. BAUDENBACHER - I. HIGGINS, *cit.*, p. 16.

⁽¹⁷⁾ S. H. ELSING, *cit.*, p. 49.

⁽¹⁸⁾ *Eco Swiss China Time Ltd v Benetton International NV*, Case C-126/97 [1999] ECR 3055. See comments of: S. BASTIANON, *L’arbitrabilità delle controversie antitrust tra diritto nazionale e diritto comunitario*, *Il Foro italiano*, 1999, IV, Col. 471; M. FURSE- L. D’ARCY, *Eco Swiss China Time Ltd / Benetton: EC Competition Law and Arbitration*, *European Competition Law Review*, 1999, p. 392; L. IDOT, *Revue de l’arbitrage*, 1999, p. 639; L. G. RADICATI DI BROZOLO, *Arbitrato, diritto della concorrenza, diritto comunitario e regole di procedura nazionali*, *Rivista dell’arbitrato*, 1999, p. 665; E. D’ALESSANDRO, *Processo arbitrale e diritto comunitario*, *Giustizia civile*, 2000, p. 1903; L. LAUDISA, *Gli arbitri e il diritto comunitario della concorrenza*, *Rivista dell’arbitrato*, 2000, p. 591; A. MOURRE, *Les rapports de l’arbitrage et du droit communautaire après l’arrêt Eco Swiss de la Cour de Justice des Communautés Européennes*, *Gazette du Palais*, 2000, p. 127; C. PUNZI, *Diritto comunitario e diritto nazionale dell’arbitrato*, *Rivista dell’arbitrato*, 2000, p. 235; N. SHELKOPLYAS, *European Community Law and International Arbitration: Logics That Clash*, *European Business Organization Law Review*, 2002, p. 569.

⁽¹⁹⁾ *Guy Denuit and Betty Cordenier v Transorient - Mosaique Voyages et Culture SA*, Case -125/04, *cit.*

the Belgian public authorities are not involved in the decision to opt for arbitration”.

5. *Arguments in support and against the traditional position of the European Court of Justice.*

From the ECJ's case law listed above, it stands out that only some arbitration bodies are able to refer questions to the Court if an issue concerning EU law is raised before them, while the majority are not.

This interpretation of the Court has been at length debated between the academics who agree with it ⁽²⁰⁾ and the ones who, on the contrary, criticize the reasoning in question ⁽²¹⁾.

The main arguments in support of the Court's position regard i) the textual interpretation of article 267 TFEU; ii) the risk of an increased workload for the Court; iii) the risk of manipulation of the preliminary ruling procedure and finally iv) the risk of a reduction in arbitral proceedings' effectiveness.

In regard to the first point, it was the UK government in the *Nordsee* decision ⁽²²⁾ who argued that the language of the Treaty refers to an official organ of the Member State, excluding thus arbitral tribunals constituted through private contracts.

The second argument consists, instead, of the concern that permitting private arbitral tribunals to refer to the Court for a preliminary ruling could lead to an excessive number of applications due to the lack of knowledge of arbitrators, who, as is known, don't have to necessarily be lawyers ⁽²³⁾. This concern was expressed in *Nordsee* ⁽²⁴⁾ by Advocate General Reischl, who stated that: “*one must reflect the risk that the Court of Justice would be burdened with a work-load the extent of which it would be difficult to estimate if it were to be thus diverted from its own work to deal with private disputes, often of very minor significance, involving some aspects of Community law*”.

Another concern is related to the fact that, since the parties have the full control of the arbitral process, they could decide to terminate it right after the request of the preliminary ruling so that they could avoid to be bound by the ECJ's statement ⁽²⁵⁾.

Finally, it has been pointed out that allowing arbitrators to request a preliminary ruling of the ECJ could undermine the effectiveness of the arbitral process,

⁽²⁰⁾ G. BEBR, *Arbitration Tribunals and Article 177 of the EEC Treaty*, CML Rev., 1985, p. 489; M. SCHWAIGER, *The Courts-Preliminary Ruling According to Article 234 EC Treaty and Arbitral Tribunals*, *Austrian Arbitration Yearbook*, 2007, p. 303.

⁽²¹⁾ M. BENEDETTELLI, “*Communitarization*” of *International Arbitration: A New Spectre Haunting Europe?*, *Arbitration International*, 2011, p. 583; S. H. ELSING, *cit.*, p. 49; L. IDOT, *cit.*, p. 287.

⁽²²⁾ *Nordsee Deutsche Hochseefischerei GmbH v Reederei Mond Hochseefischerei Nordstern AG & Co. KG and Reederei Friedrich Busse Hochseefischerei Nordstern AG & Co. KG*, Case 102/81, *cit.*

⁽²³⁾ S. H. ELSING, *cit.*, p. 51.

⁽²⁴⁾ *Nordsee Deutsche Hochseefischerei GmbH v Reederei Mond Hochseefischerei Nordstern AG & Co. KG and Reederei Friedrich Busse Hochseefischerei Nordstern AG & Co. KG*, Case 102/81, *cit.*

⁽²⁵⁾ M. SCHWAIGER, *cit.*, p. 307.

since the procedure before the Court can last for years and might not guarantee the secrecy, considering that speed and confidentiality are factors that the parties take into consideration in choosing arbitration ⁽²⁶⁾.

These theories didn't persuade part of the academic community, which believes instead that private arbitrators should have the right to refer questions to the Court under article 267 TFEU.

Generally speaking, the importance of arbitration in international business transactions has been remarked, where going before an arbitrator doesn't always correspond to a free choice of the parties, but often is *de facto* the only way to solve disputes ⁽²⁷⁾.

Hence, given the importance of arbitration in an always higher number of commercial sectors, ensuring the compliance of the awards with the EU law in order to avoid the risk of their annulment and to contribute to its uniform application becomes crucial ⁽²⁸⁾.

Regarding the concerns about a potential increase in the Court's workload or about the risk that the parties terminate the arbitration process after the ECJ's ruling, these cannot be considered decisive enough to deny to arbitral tribunals the right under article 267 TFEU. Indeed the same issues could arise even if the request for the preliminary ruling was made by the national courts when they act in support of the arbitrators or during the review of the award.

Not even the argument based on the presumed absence of a link between private arbitrators and state authorities, stressed by the Court in *Nordsee* ⁽²⁹⁾, seems to be well-founded. Indeed the possibility to opt for arbitral tribunals instead of ordinary state courts derives from procedural laws of the Member States ⁽³⁰⁾, which enable arbitral tribunals to issue enforceable arbitral awards that have the same effects of the ordinary courts of law ⁽³¹⁾.

Futhermore, a strict application of the *Vaasee*'s requirements could imply that every time an ordinary judge decides in equity, thus without applying rules of law, he is not allowed to refer to the Court for a preliminary ruling even if he fulfils all the other elements.

Many doubts concern, finally, the effectiveness of the "*golden bridge*" alternative suggested by the Court as an indirect possibility for an arbitral tribunal to ask a preliminary ruling. This option not only imposes an additional workload on state courts, but simply postpones the moment of the request for the ECJ's ruling, causing a considerable waste of time and resources ⁽³²⁾. Moreover, this method

⁽²⁶⁾ S. H. ELSING, *cit.*, p. 53.

⁽²⁷⁾ C. BAUDENBACHER, *Judicial of European competition law, International Antitrust Law & Policy: Fordham Corporate Law*, 2002, 2003, p. 363.

⁽²⁸⁾ M. BENEDETTELLI, *cit.*, p. 585.

⁽²⁹⁾ *Nordsee Deutsche Hochseefischerei GmbH v Reederei Mond Hochseefischerei Nordstern AG & Co. KG and Reederei Friedrich Busse Hochseefischerei Nordstern AG & Co. KG*, Case 102/81, *cit.*

⁽³⁰⁾ I.e. in Italy and France the rules which regulate arbitration are contained in the Code of Civil Procedure, in particular from art. 806 to art. 840 of the Italian Code and from art. 1442 to art. 1527 of the French Code.

⁽³¹⁾ S. H. ELSING, *cit.*, p. 56.

⁽³²⁾ J. D. M. LEW - L. A. MISTELIS - S. KRÖLL, *Arbitration and European Law, Comparative International Commercial Arbitration*, 2003, p. 477.

presupposes that national arbitration or procedural rules permit arbitral tribunals to seek request for court assistance, as i.e. in the German legal system, otherwise there is no real alternative to a direct right of the arbitral tribunals pursuant to Article 267 TFEU.

6. *Conclusion.*

The order of the ECJ in comment doesn't seem to revolutionize the traditional approach established in the case law described above. However, it introduces some elements that suggest more openness from the Court to the possibility of admitting the referral of a preliminary ruling from arbitral tribunals.

The Court in fact considered overcoming some characteristics such as the fact that the parties had the freedom of varying the composition and the rules of the Tribunal's procedure and that it had been dissolved after making its decision, where traditionally they were considered as a barrier for the admissibility of the referral for a preliminary ruling.

However, what stands out for the Court's reasoning in deciding in favour of the admissibility was mainly the fact that the Tribunal Arbitral necessário was established by law. The difference between a state-organized and a non-statutory arbitral tribunal is still decisive in the opinion of the ECJ.

Although it is clear that opening up the opportunity for private arbitral tribunals to refer to the ECJ for a preliminary ruling could lead to some issues, the arguments in support of the Court's position don't seem to be insurmountable.

On the contrary the need to contribute to the correct and uniform application of EU law seems even more pertinent: it is maybe worth more to extend the length of the arbitral process in order to obtain an award, which complies with EU law and hence does not run the risk of annulment.

In conclusion, it is desirable that the Court reconsiders its position, finally allowing a non-statutory arbitral tribunal to request a preliminary ruling under the article 267 TFEU.

SIMONA PELLERITI